

**REMARKS**

Upon entry of the present amendment, claims 11-16 will be pending. Claims 1-10 are canceled without prejudice or disclaimer. New claims 11-16 have been added and are fully supported by the instant specification as filed. No new matter is added.

***Rejection Under 35 U.S.C. § 112, Second Paragraph***

The Office has rejected claim 8 for alleged indefiniteness. Applicants submit that the rejection of claim 8 is rendered moot by the cancellation of that claim. Withdrawal of the rejection under § 112, second paragraph is respectfully requested.

***Rejection Under 35 U.S.C. § 103(a)***

Claims 1-10 have been rejected for alleged obviousness over U.S. Pat. No. 5,712,295 to Mencke, *et al.* (“the U.S. Mencke patent”) in view of WO 96/38165 to Mencke, *et al.* (“the Mencke publication”). The rejection of claims 1-10 is rendered moot by the cancellation of such claims, and withdrawal of the rejection for alleged obviousness is respectfully requested.

Applicants have introduced new claims 11-16 and submit that such claims are allowable over the prior art, including the U.S. Mencke patent and the Mencke publication, either alone or in combination. As acknowledged by the Office, the U.S. Mencke patent discloses compositions comprising agonists and antagonists of the nicotinic acetyl-choline receptors, and teaches that such compositions can be administered to animals that are afflicted with any of a number of different pathogenic endoparasites (*see* U.S. Mencke patent at column 6, line 21 to column 7, line 40). The Office has likewise acknowledged that the Mencke publication discloses compositions comprising avermectins or milbemycins, and teaches that such compositions can be administered to animals that are afflicted with any of a number of different endoparasites (*see* Mencke publication at Abstract and pages 16-18).

In contrast to the cited references, which are both directed to providing compositions for treating *only* an endoparasitic infection, new claims 11-16 are directed to methods for treatment of an animal having *both* an endoparasitic infection *and* an ectoparasitic infection. Neither of the cited references teaches or suggests the treatment of an animal having an ectoparasitic infection, *much less* the treatment of an individual animal that is infected

simultaneously with *both* endoparasites *and* ectoparasites. Thus, even if one skilled in the art were motivated to combine the two cited references, it would not have been for the purpose embodied in applicants' method claims. As such, the presentation of these method claims renders inapposite the case of *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (cited by the Office in the 9/23/08 Office Action at page 3). *Kerkhoven* states that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, *in order to form a third composition to be used for the very same purpose*" (emphasis added). *Kerkhoven* was directed to composition claims. It does not apply to the present claims, which are based on a composition directed to a purpose different from that either one of the references suggest.<sup>1</sup>

In order to present a *prima facie* case of obviousness with respect to a given claim, the Office must demonstrate that every single element in such claim is either taught or suggested in the cited prior art. Here, however, the cited references, even in combination, fail to teach or suggest the administration of the recited active ingredients to an animal having an ectoparasitic infection, much less to an animal having an endoparasitic infection and an ectoparasitic infection, as required by the present claims. A rejection of the present claims over the combination of the U.S. Mencke patent and the Mencke publication would impermissibly disregard an explicit element of claim 11 that is not taught or suggested by the cited references. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a *prima facie* case of obviousness).

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<sup>1</sup> In parallel with the citation to *In re Kerkhoven*, M.P.E.P. § 2144.06 cites two additional cases holding that combining two components, each of which was taught by the prior art to be useful for the same purpose, in order to form a third composition that is useful *for the very same purpose*, is *prima facie* obvious. *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960), determined that claims directed to the production of cast iron that was produced with a mixture of calcium carbide and magnesium oxide and in which the graphitic carbon was wholly or partly in the form of nodules was unpatentable over prior art in which these components individually produced a nodular structure in cast iron. *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992), determined that claims directed to a herbicidal composition comprising two known herbicides were *prima facie* obvious. None of these cases stands for the proposition, nor is there any support for the proposition, that a combination of references, each of which teaches the use of a separate compound for one purpose, renders *prima facie* obvious claims to a method that uses a combination of the compounds for a different purpose.

The Office has not provided any objective evidence or reasoning to support the contention that it would have been obvious to one skilled in the art to combine the respective teachings of the cited reference in such a manner as to produce any claimed invention, and accordingly a prima facie case of obviousness has not been presented.

Even if a prima facie case of obviousness had been presented (a point not conceded by the Applicants), it is rebutted by the specification of the application and by the declaration of Dr. Andreas Turberg filed with Applicants' Reply dated September 10, 2008, which together demonstrate that the co-administration of the first and second active ingredients specified in the pending claims produces unexpectedly beneficial results. Examples A through E in the present application collectively demonstrate that co-administration of the first and second active ingredients in various respective dosages provide better control of ectoparasites, endoparasites, or both than does separate administration of compounds that are equivalent to either the first active ingredient only or the second active ingredient only (*see* 9/10/08 Reply page 6). Likewise, the declaration of Dr. Turberg demonstrates that the administration of two different combinations of first and second active ingredients (namely, the administration of moxidectin with imidacloprid, and the administration of eprinomectin and thiametoxam) results in unexpectedly improved efficacy against parasitic infection as compared with administration over the respective active ingredients alone (*see* 9/10/08 Reply pages 6-7).

The Office has suggested that the evidence presented in the instant specification and in the declaration of Dr. Andreas Turberg do not suffice to demonstrate unexpected or synergistic results for the full scope of the former claims (9/23/08 Office Action at page 4). However, Applicants' need not demonstrate unexpected results with respect to every species within a claimed genus, as long as one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. *See* M.P.E.P. § 716.02(d). Pending claims 11-16 encompass only those species that are fairly represented by the synergistic data of record. One skilled in the art would readily appreciate that the compositions exemplified in the instant application and in the declaration of Dr. Andreas Turberg constitute a representative subset of the relatively narrow genera recited in the pending claims, and that the nonobviousness of the full scope of claims 11-16 is supported (in addition to the reasons provided above) by the unexpected

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results described therein. To the extent that the Office would contend that the contrary is true, it is evident that the Office would be applying an unduly strict nonobviousness standard that is not authorized by the applicable rules for patent examination. Accordingly, for at least this reason as well, newly introduced claims 11-16 should be found nonobvious and therefore patentable over the prior art of record.

***Conclusion***

Applicants believe that the foregoing constitutes a complete and full response to the pending Office Action and that the pending claims are in condition for allowance. Accordingly, an indication of allowability of the pending claims is respectfully requested.

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/David B. Hoffman/

David B. Hoffman

Registration No. 62,835

Woodcock Washburn LLP  
Cira Centre  
2929 Arch Street, 12th Floor  
Philadelphia, PA 19104-2891  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439